

EN

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Answer given by Ms Kyriakides
on behalf of the European Commission
(28.11.2024)

The Commission is aware of supply challenges related to isotonic saline solutions in the EU. To respond to critical shortages of medicines, including isotonic saline solutions, the European Medicines Agency (EMA) and the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) continuously monitor and investigate signals of (potential) supply disruptions escalated to EU level by national competent authorities. In this context, EMA is currently evaluating the supply situation of isotonic saline solutions across EU/European Economic Area countries and potential impact on patients and users. The potential effect on prices depends on the national context, as pricing and reimbursement of medicines are the responsibility of Member States. After assessing the situation in the different countries, EMA and MSSG will determine if actions should be taken at EU level to respond to potential shortages of these medicines.

Any actions would be taken ahead of the revision of the pharmaceutical legislation currently under negotiation¹. Regarding shortages, the Commission has proposed to reinforce the role and powers of EMA² and MSSG³ to take actions in case of (potential) critical shortages of medicines outside crises times. More specifically, the Commission has proposed to strengthen the obligation to notify potential shortages early, require companies to have shortage prevention plans for all medicines, and introduce additional tools to monitor and mitigate risks of shortages for critical medicines on a Union list⁴.

¹ https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en

² <http://data.europa.eu/eli/reg/2022/123/oj>

³ <https://www.ema.europa.eu/en/about-us/what-we-do/crisis-preparedness-management/executive-steering-group-shortages-medicinal-products/executive-steering-group-shortages-safety-medicinal-products-mssg-meetings>

⁴ <https://www.ema.europa.eu/en/news/first-version-union-list-critical-medicines-agreed-help-avoid-potential-shortages-eu>